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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/754,347	01/05/2001	Daniel Gelber	XMP 2037	3297

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ARLINGTON, VA 22202

EXAMINER

WITZ, JEAN C

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 06/30/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/754,347

Applicant(s)

GELBER ET AL.

Examiner

Jean C. Witz

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-~~6~~, 9-49, 54-60, 62-102 and 107-115 is/are pending in the application.
- 4a) Of the above claim(s) 9-49, 60 and 62-102 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 54-59 and 103-115 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 9. 6) ☐ Other:

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DETAILED ACTION

Response to Arguments

Applicant's arguments filed April 17, 2003 have been fully considered but they are not persuasive for the reasons set forth below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-6, 54-59, 103-106 and 113-115 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wiersma (5,948,414), Hamel et al. (4,662,880), Ayer et al. (4,810,502) and Weinstein (6,270,796) combined with Armstrong et al. (6,255,294) for the reasons of record.

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Newly added limitation requires that the anti-inflammatory nutraceutical be the only anti-inflammatory agent present in the composition and include other components selected from the group consisting of immune boosters, antioxidants and/or liver protectants.

In review, the primary references (Wiersma (5,948,414), Hamel et al. (4,662,880), Ayer et al. (4,810,502) and Weinstein (6,270,796)) all disclose multiple variations and combinations of conventional anti-histamines and conventional decongestants for treatment of rhinitis from allergies and colds. These references are essentially duplicative. Further, none of the references teach a composition that contains a pharmaceutical NSAID, such as acetaminophen or ibuprofen.

Armstrong et al. discloses that stinging nettle is conventionally included in a composition for treatment of allergies. See col. 4, lines 43-48. Armstrong also includes ascorbic acid (Vitamin C) which is an anti-oxidant within the meaning as Applicant defines it.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine stinging nettle with other conventional allergy treating drugs including other antihistamines as well as conventional decongestants. "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

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Applicants argue that Armstrong "fails to provide any teaching that would lead one of ordinary skill in the art to the conclusion that stinging nettle aids in the maturation of immune system cells in the absence of Vitamin B12." This argument is neither germane nor persuasive. The patent teaches the inclusion of stinging nettle in a composition for treating allergies. The inclusion of this component is optional; therefore, there is no teaching, either explicit or implied, that Vitamin B12 must be present along with the stinging nettle. Further, Applicants' open claim language allows for the inclusion of other ingredients.

Applicants also assert the advantages of substituting an herbal anti-inflammatory for a NSAID. Again, this argument is not persuasive. In response to this argument, the fact that applicants have recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). In this case, as stated above, it is prima facie obvious to combine several compositions, each of which is taught by the prior art to be useful for the same purpose, in order to form a final composition to be used for the very same purpose. So long as the Examiner provides a prima facie case of obviousness, it need not be the same reason that Applicants formulated the claimed composition.

Claims 107-109 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wiersma (5,948,414), Hamel et al. (4,662,880), Ayer et al. (4,810,502) and Weinstein (6,270,796) combined with Armstrong et al. (6,255,294) as applied to claims 1-6, 54-59, 103-106 above, and further in view of Thomas et al. (5,972,985).

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The composition requires the inclusion of a liver protectant, specifically milk thistle. At col. 7, Thomas et al. teach that flavonoid phytonutrients enhance the effects of ascorbate-Vitamin C. Among the most useful flavonoids is silybin, also known as milk thistle. The patent states that the biologic activities of flavonoids include action against allergies, inflammation, free radicals, hepatotoxins, platelet aggregation, microbes, ulcers, viruses and tumors.

It would have been obvious to one of ordinary skill in the art to include milk thistle for its known enhancement of the effects of Vitamin C in the claimed composition as well as for its known action against allergies. Since Applicants are defining milk thistle as outside the definition of anti-inflammatory agent for the purposes of their invention, the inclusion of milk thistle (even in view of its anti-inflammatory properties) is not deemed to be excluded by the claim language.

Claims 110-109 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wiersma (5,948,414), Hamel et al. (4,662,880), Ayer et al. (4,810,502) and Weinstein (6,270,796) combined with Armstrong et al. (6,255,294) as applied to claims 1-6, 54-59, 103-106 above, and further in view of Bryce-Smith (5,688,532).

The composition further requires the inclusion of an immune booster. Bryce-Smith teaches that zinc is a simple, cheap and efficient treatment for an allergic condition. See the abstract.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine zinc with other conventional allergy treating

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compositions including other antihistamines as well as conventional decongestants. "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

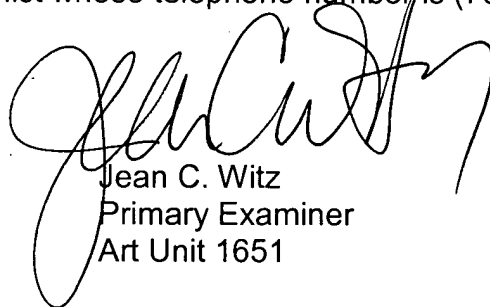
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jean C. Witz whose telephone number is (703) 308-

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3073. The examiner can normally be reached on 6:30 a.m. to 4:00 p.m. M-Th and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (703) 308-4743. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Jean C. Witz
Primary Examiner
Art Unit 1651

June 29, 2003